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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,025	11/21/2003	Elliot Lorne Chaikof	133-02	3169

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GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,025	CHAIKOF ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods and products. The methods and agents/products rely upon synthetic protein copolymers of different structural variations but that have at the very minimum at least one hydrophilic block and at least one hydrophobic. However, the products ultimately differ in structure and the methods differ in modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species. Applicant is invited to clearly elect a single Group as it reads on a particular protein copolymer or method that uses said protein copolymer and to provide an appropriate claim that reads on the elected invention. The Groups set forth below appear to read on the claims as currently recited, but may be subject to further Restriction and/or species election depending on the claimed recitation.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 11-19, 33-40 and 41-43, drawn to a protein copolymer with a two hydrophobic end blocks and a middle hydrophilic block, classified in class 424, subclass 400.

A. Claim 3, drawn to drawn to a protein copolymer with two identical hydrophobic end blocks and a middle hydrophilic block, classified in class 424, subclass 400.

B. Claims 4 and 8, drawn to a protein copolymer with two hydrophobic end blocks and a middle hydrophilic block where the first hydrophobic end block is selected from SEQ ID Nos: 11 or 12, classified in class 424, subclass 400. Applicant is required to elect a single sequence for the first end block. N.B. This is **NOT** an election of species.

C. Claim 5, drawn to a protein copolymer with a two hydrophobic end blocks and a middle hydrophilic block wherein the middle block is selected from a group consisting of SEQ ID Nos: 14, 15 or 18, classified in class 424, subclass 400. Applicant is required to elect a single sequence for the middle block. N.B. This is **NOT** an election of species.

D. Claims 6 and 7, drawn to a protein copolymer with a two hydrophobic end blocks and a middle hydrophilic block wherein the first hydrophobic end block is selected from SEQ ID Nos: 11 or 12 and the middle block is selected from SEQ ID Nos: 14, 15 or 18, classified in class 424, subclass 400. Applicant is required to elect a single sequence for the first end block (e.g. 11 or 12) and a single sequence for the middle block (e.g. 14, 15 or 18). N.B. This is **NOT** an election of species.

E. Claims 9 and 10, drawn to a protein copolymer with two hydrophobic end blocks and a middle hydrophilic block wherein the middle

block is selected from SEQ ID Nos: 21, 23, 24, 25, 30, 33, 35, 38, 41, 42, 43 or 63 and where in the first end block is selected from SEQ ID Nos: 11 or 12, classified in class 424, subclass 400. Applicant is required to elect a single sequence for the middle block and a single sequence for the first end block. N.B. This is **NOT** an election of species.

F. Claim 29, drawn to a film comprising a protein copolymer fiber and a fiber that is synthetic or natural wherein the protein copolymer has two hydrophobic end blocks and one hydrophilic middle block, classified in class 424, subclass 433.

II. Claim 30, drawn to a film comprising a protein copolymer fiber and a drug or biologically active compound, classified in class 424, subclass 443.

III. Claims 19, 20 and 31, drawn to a fiber network comprising a first and second fiber, classified in class 424, subclass 443.

IV. Claims 44 and 45, drawn to a cell encapsulated by a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

V. Claims 44 and 45, drawn to a tissue encapsulated by a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

VI. Claims 44 and 45, drawn to an organ encapsulated by a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

VII. Claims 46, 48 and 49, drawn to a non-covalently crosslinked synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

VIII. Claims 47, and 50-56, drawn to a covalently crosslinked synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block wherein the covalent crosslink is between lysines, classified in class 424, subclass 400.

IX. Claims 47 and 50-56, drawn to a covalently crosslinked synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block wherein the covalent crosslink is between glutamines, classified in class 424, subclass 400.

X. Claims 57-59, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a functional site capable of serving as a binding site, classified in class 424, subclass 400.

XI. Claim 60, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a metal binding site, classified in class 424, subclass 400.

XII. Claim 60, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising an inorganic ion nucleation binding site, classified in class 424, subclass 400.

XIII. Claim 61, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising an adhesion molecule recognition site, classified in class 424, subclass 400.

XIV. Claim 61, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising an enzyme active site binding site, classified in class 424, subclass 400.

XV. Claim 62 and 63, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising an agent wherein the agent is a drug, classified in class 424, subclass 400.

XVI. Claim 62 and 63, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising an agent wherein the agent is a biologically active molecule, classified in class 424, subclass 400.

XVII. Claim 64-67, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a saccharide, classified in class 424, subclass 400.

XVIII. Claim 64-67, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a oligosaccharide, classified in class 424, subclass 400.

XIX. Claim 64-67, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a polysaccharide, classified in class 424, subclass 400.

XX. Claim 64-67, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a glycopolymer, classified in class 424, subclass 400.

XXI. Claim 64-67, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a ionic synthetic polymer, classified in class 424, subclass 400.

XXII. Claim 64-67, drawn to drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising a non-ionic synthetic polymer, classified in class 424, subclass 400.

XXIII. Claim 64-67, drawn to a synthetic protein copolymer comprising at least one hydrophilic block and at least one hydrophobic block and further comprising an organic molecule, classified in class 424, subclass 400.

XXIV. Claims 21, 71 and 72, drawn to a method of generating a medical implant comprising using fiber networks, classified in class 424, subclass 423.

N.B. Applicant is required to elect a single sequence from SEQ ID Nos: 45, 46, 47 or 48. This is **NOT** an election of species.

XXV. Claims 22-24 and 27, drawn to a method for producing a plastic elastic protein copolymer, classified in class 530, subclass 333.

XXVI. Claims 25 and 68-70, drawn to a method of manufacture of an implanted biomedical device, classified in class 424, subclass 423.

XXVII. Claim 26, drawn to a nucleic acid sequence comprising SEQ ID Nos: 45, 46, 47 or 48, classified in class 536, subclass 23.1. N.B. Applicant is required to elect a single sequence. This is **NOT** an election of species.

XXVIII. Claim 28, drawn to a medical device comprising a protein copolymer film, classified in class 424, subclass 423.

XXIX. Claim 28, drawn to a cell tissue comprising a protein copolymer film, classified in class 424, subclass 422.

XXX. Claim 28, drawn to an organ further comprising a protein copolymer film, classified in class 424, subclass 422.

XXXI. Claim 32, drawn to a medical device at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 423.

XXXII. Claim 32, drawn to a cell tissue at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 422.

XXXIII. Claim 32, drawn to an organ at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 422.

XXXIV. Claims 73-76, drawn to a method of generating a wound dressing , classified in class 424, subclass 445.

XXXV. Claims 74 and 75, drawn to a method of generating a medical implant by applying a protein copolymer film to the medical implant, classified in class 424, subclass 423.

3. Claim 1 links inventions I-XXXV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claim 1. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Applicants should note that Claims 2, 11-19, 33-40 and 41-43 (Group I) further links inventions A-I. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1, 2, 11-19, 33-40 and 41-43. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant

application. In order for the claims from Groups A-F to be considered, Applicants must first elect Group I, and subsequently elect one Group from A-F.

The inventions are distinct, each from the other because of the following reasons:

5. Inventions IA-IF are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each product has its own unique structure that is not an obvious variant of each of the other products, and each product has a its own function and mode of action and design. As such, each product is patentably distinct.

6. Inventions I, II-XXIII and XXVII-XXXIII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each product has its own unique structure that is not an obvious variant of each of the other products, and each product has a its own function and mode of action and design. Thus, the search of each different product will not be coextensive and would place an undue search burden upon the examiner.

7. Inventions XXIV-XXVI and XXXIV-XXXV are directed to related methods of design and/or producing the products of Groups (I, II-XXIII and XXVII-XXXIII). The

related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each method has its own unique method steps which ultimately has different end points. For instance, the method of producing a medical implant and a method of generating a wound dressing will have unique and materially different products involved in the method steps. Thus a search for each different method will not be co-extensive and thus will add an extra search burden to the examiner.

8. Inventions [I, II-XXII, XXVII-XXXIII] and [XXIV-XXVI, XXXIV-XXXV] are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as claimed can be made materially different processes and the methods can be used to make materially different products simply by utilizing different materials in the method of manufacture or making. As such, the products and methods are distinct and not necessarily co-extensive in each of their searches which would place an undue search burden upon the examiner.

9. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Potential Right to Rejoinder

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is

571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SMN
14 June 2006

ROBERT A. WAX
PRIMARY EXAMINER